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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,254	04/09/2004	Shahriar Shane Taremi	JB06017US01	1701

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033-0530

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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10/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,254	TAREMI ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 14, 15, 28, 30 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 14, 15, 28, 30 and 34-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1] Claims 1-2, 14-15, 28, 30, and 34-39 are pending in the application.
- [2] Applicant's amendment to the claims, filed on 9/6/07, is acknowledged. Claims 1-2, 14-15, 28, and 30 are amended and claims 36-39 are newly added. Claims 3-13, 16-27, 29, and 31-33 were canceled in a prior amendment. The claim listing filed on 9/6/07 replaces all prior versions and listings of the claims.
- [3] Applicant's amendment to the specification, filed on 9/6/07, is acknowledged.
- [4] Applicant's arguments filed on 9/6/07 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Specification/Informalities

- [6] The objection to the specification as being unclear in stating "SCH549128" is withdrawn in view of the amendment to the specification to delete "SCH549128" and applicant's accompanying remarks (beginning at p. 14, top); which state that the compound previously referred to as "SCH549128" in the specification is the same as the compound referred to as "Ac-⁶⁴Cl₂WAC₃₀E". The examiner agrees with applicant's position that for reasons presented by applicant beginning at p. 14 of the instant remarks, a

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skilled artisan would recognize that the compound referred to as "SCH549128" in the specification is the same as the compound "Ac-^{6Cl}WAC_{3C}E".

[7] The specification is objected to as the compound shown at p. 38 does not have proper valency for nitrogens (valency = 3) and oxygens of the carboxy groups (valency = 2). For example, a skilled artisan would recognize the oxygens of the carboxy groups should have either a negative charge or a bonded hydrogen. Appropriate correction is requested.

Claim Objections

[8] The objection to claims 1, 14, and 28 because the oxygens of the carboxy groups do not have proper valency is withdrawn in view of the claim amendment to add a negative charge to the oxygens of the carboxy groups.

[9] Claims 1, 14, 28, and 30 are objected to as the recited compound does not have proper valency for nitrogen atoms (nitrogen valency = 3). Appropriate correction is requested.

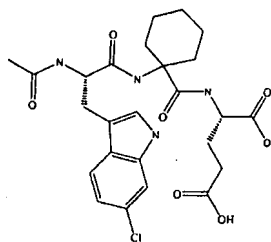
Claim Rejections - 35 USC § 112, Second Paragraph

[10] The rejection of claims 28 and 30 under 35 U.S.C. 112, second paragraph, as being inconsistent in identifying compounds in the specification and claims 28 and 30 that have distinct structures is withdrawn in view of the claim amendment to delete the term "Ac-^{6Cl}WAC_{3C}E".

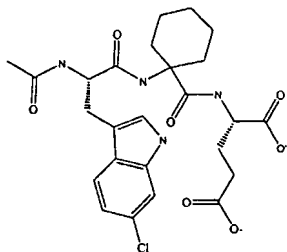
Claim Rejections - 35 USC § 112, First Paragraph

[11] The new matter rejection of claim(s) 1-2 and 15 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendment to claim 1 to limit the polypeptide of claim 1 to "A soluble purified polypeptide comprising the amino acid sequence of SEQ ID NO:10"; to amend claim 2 so that it is an independent claim and no longer depends from claim 1; and to limit the polypeptide of claim 15 to "said polypeptide comprises the amino acid sequence of SEQ ID NO:10". It is noted that according to the specification, SEQ ID NO:10 is the HDM2 (F55Y/Y76H) polypeptide referred to in Example 2 beginning at p. 45, bottom. See particularly p. 41, Table 2.

[12] The new matter rejection of claims 28, 30, and 34-35 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendment to the claims to replace the compound shown as:



with the following compound:



[13] The written description rejection of claims 1-2, 15, 28, 30, and 34-35 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See particularly paragraph 11 beginning at p. 7 of the Office action mailed on 4/6/07. Claim 14 is included in the instant rejection in view of the amendment for reasons set forth below. Newly added claims 36-39 are included in the instant rejection for reasons set forth below. Thus, claims 1-2, 14-15, 28, 30, and 34-39 are rejected herein.

RESPONSE TO ARGUMENT: Applicant argues the rejection is obviated by amendment to: 1) characterize the genus of proteins as recited in claims 1, 2 (claims 36-39 dependent therefrom), and 15 as "soluble" and 2) replace "having" with "consisting of" in claims 28 (claim 34 dependent therefrom) and 30 (claim 35 dependent therefrom).

Applicant's argument is not found persuasive. Regarding argument 1), it is acknowledged that the examiner may have previously implied that characterizing the protein of claims 1, 2, and 15 as being "soluble" would overcome the instant rejection (see p. 10, paragraph 12 of the Office action mailed on 4/6/07). However, it is noted that upon further consideration of the meaning of "soluble", it is the examiner's position that the term "soluble" does not necessarily require that the protein be solubilized, but can be interpreted as meaning, *e.g.*, being amenable to being solubilized, having the ability to be solubilized, or being capable of being solubilized. In the interest of compact prosecution, the examiner suggests replacing the term "soluble" with "non-crystalline."

Regarding argument 2), the examiner acknowledges the claim amendment to replace the open-ended transitional phrase “having” with the closed transitional phrase “consisting of”. To the extent the rejection was based on the recitation of “having”, the rejection is withdrawn. However, it is noted that claims 14 (claim 15 dependent therefrom), 28 (claim 34 dependent therefrom), and 30 (claim 35 dependent therefrom) have been amended to recite “a compound *represented by* the structural formula...” (emphasis added).

According to Webster’s online dictionary (Webster.com, last viewed on 10/23/07), the term “represent” can mean “to serve as a specimen, example, or instance of”. MPEP 2163.II.A.1 states that in evaluating a claimed invention for adequate written description, the examiner should determine what the claim as a whole covers. “Claim construction is an essential part of the examination process. Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description. See, e.g., *In re Morris*, 127 F.3d 1048, 1053-54, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).” In view of the dictionary definition of “represent”, the recitation of “A compound represented by the structural formula...” has been broadly and reasonably interpreted as encompassing a genus of compounds, wherein the compound(s) shown in claims 14, 28, and 30 has been interpreted as being exemplary, *i.e.*, a species, of the recited genus. Other than the two disclosed species of compounds as shown in, e.g., claim 14, the specification fails to disclose any other compounds of the genus of compounds of claim 14. Also, other than the single disclosed species of crystals of SEQ ID NO:6 or 10 complexed with the compound

shown in claim 28, the specification fails to disclose any other crystals of compounds complexed with SEQ ID NO:6 or 10. In view of a broad, but reasonable interpretation of the phrase "A compound represented by the structural formula...", the genus encompasses widely variant species, encompassing essentially any compound having any structure, including small organic molecules and polypeptides such as antibodies. However, the disclosed species as noted above are not seen to reflect the substantial variation within the genus and thus are not deemed to be representative of the genus. Given the lack of description of a representative number of polypeptides, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[14] The scope of enablement rejection of claims 1-2 and 15 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See particularly paragraph 12 beginning at p. 10 of the Office action mailed on 4/6/07. In view of applicant's arguments, the enablement rejection of claims 28, 30, and 34-35 is withdrawn and the claims are included herein for reasons that follow. Claim 14 is included in the instant rejection in view of the amendment for reasons set forth below. Newly added claims 36-39 are included in the instant rejection for reasons set forth below. Thus, claims 1-2, 14-15, 28, 30, and 34-39 are rejected herein.

RESPONSE TO ARGUMENT: Applicant argues the rejection is obviated by amendment to: 1) characterize the genus of proteins as recited in claims 1, 2 (claims 36-39 dependent therefrom), and 15 as "soluble" and 2) replace "having" with "consisting of" in claims 28 (claim 34 dependent therefrom) and 30 (claim 35 dependent therefrom).

Applicant's argument is not found persuasive. Regarding argument 1), it is acknowledged that the examiner may have previously implied that characterizing the protein of claims 1, 2, and 15 as being "soluble" would overcome the instant rejection (see p. 10, paragraph 12 of the Office action mailed on 4/6/07). However, it is noted that upon further consideration of the meaning of "soluble", it is the examiner's position that the term "soluble" does not necessarily require that the protein be solubilized, but can be interpreted as meaning, e.g., being amenable to being solubilized, having the ability to be solubilized, or being capable of being solubilized. In the interest of compact prosecution, the examiner suggests replacing the term "soluble" with "non-crystalline."

Regarding argument 2), the examiner acknowledges the claim amendment to replace the open-ended transitional phrase "having" with the closed transitional phrase "consisting of". To the extent the rejection was based on the recitation of "having", the rejection is withdrawn. However, it is noted that claims 14 (claim 15 dependent therefrom), 28 (claim 34 dependent therefrom), and 30 (claim 35 dependent therefrom) have been amended to recite "a compound *represented by* the structural formula..." (emphasis added).

According to MPEP 2164.04, “[b]efore any analysis of enablement can occur, it is necessary for the examiner to construe the claims...and explicitly set forth the scope of the claim when writing an Office action.” Also, MPEP 2164.08 states, “[a]ll questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim is enabled. Accordingly, the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims...claims are to be given their broadest reasonable interpretation that is consistent with the specification.” As noted above, in view of the dictionary definition of “represent”, the recitation of “A compound represented by the structural formula...” has been broadly and reasonably interpreted as encompassing any compound, wherein the compound(s) shown in claims 14, 28, and 30 has been interpreted as being exemplary, *i.e.*, a working example, of the scope of recited compounds. Other than the two disclosed working examples of compounds as shown in, *e.g.*, claim 14, the specification fails to disclose any other compounds as encompassed by claim 14. Also, other than the single working example of crystals of SEQ ID NO:6 or 10 complexed with the compound shown in claim 28, the specification fails to disclose any other crystals of compounds complexed with SEQ ID NO:6 or 10. In view of a broad, but reasonable interpretation of the phrase “A compound represented by the structural formula...”, the claims encompass essentially any compound having any structure, including small organic molecules and polypeptides such as antibodies. However, the disclosed working examples as noted above and the guidance provided

by the specification and prior art are not seen to provide the necessary guidance for a skilled artisan to make and use all compounds as broadly encompassed by the claims.

In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability as evidenced by the prior art, and the amount of required experimentation, it is the examiner's position that undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

[15] The enablement rejection of claims 28, 30, and 34-35 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's argument (instant remarks at pp. 17-18) that: 1) the compound previously referred to as "SCH549128" in the specification is the same as the compound referred to as "Ac-⁶ClWAC₃C₃E" (see also the examiner's comments addressing specification objection above) and 2) the specification provides guidance regarding the concentration of Ac-⁶ClWAC₃C₃E used for making the crystal of claim 30 and further provides an expectation of success for making such crystal as

demonstrated in Example 3 beginning at p. 63 of the specification. As noted above, claims 28, 30, and 34-35 have been included in the scope of enablement rejection.

Examiner Comment/Clarification

[16] It is noted that the instant specification fails to disclose a method for making the compounds disclosed at p. 38 of the specification. However, the disclosed compounds are a tripeptide of (acetylated 6-chloro-tryptophan)-(1-aminocyclohexanecarboxylic acid)-(glutamate) or (acetylated 6-bromo-tryptophan)-(1-aminocyclohexanecarboxylic acid)-(glutamate). Each of the amino acids of the peptides appears to be commercially available and methods for peptide synthesis were well-known in the art at the time of the invention. As such, it is the examiner's position that the specification need not expressly disclose a method for producing the compounds as disclosed at p. 38.

Conclusion

[17] Status of the claims:


- Claims 1-2, 14-15, 28, 30, and 34-39 are pending.
- Claims 1-2, 14-15, 28, 30, and 34-39 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656